

REMARKS

Claims 1, 2 and 4-13 are pending in the present application. Claims 6-13 have been constructively elected for further prosecution and claims 1, 2, 4 and 5 have been withdrawn from consideration. Claims 6-13 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious by U.S. Patent No. 4,610,688 to Silvestrini ("Silvestrini) in view of U.S. Patent No. 4,279,249 to Vert ("Vert") or U.S. Patent No. 4,743,257 to Tormala ("Tormala").

Election/Restriction

According to the Examiner, amended claims 1, 2, 4 and 5 are directed to an invention that is independent or distinct from the invention originally claimed because "the claims are no longer directed to an internally reinforced biodegradable material but are directed to uniaxially or biaxially oriented polymers." The Examiner further states that since newly added claims 6-13 are directed to the scope of the elected invention and since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. As a result, the Examiner has withdrawn claims 1, 2, 4 and 5 from consideration.

Applicants traverse this restriction requirement and respectfully disagree with the Examiner's analysis as claims 1, 2, 4 and 5 are is no way directed to an invention independent and distinct from the originally claimed subject matter. Particularly, Examiner's statement that "the claims are no longer directed to an internally reinforced biodegradable material but are directed to uniaxially or biaxially oriented polymers" seems to indicate that the Examiner believes that a material that is "internally reinforced" and a material that comprises a "uniaxially or biaxially oriented polymer" are mutually exclusive. Based on the specification, it is clear that a uniaxially or biaxially oriented polymer is a type of internally reinforced material. See page 8, line 24 to page 9, line 2. Accordingly, Applicants submit that claims 1, 2, 4, and 5 are not independent and distinct

from the invention as originally presented and that a constructive election of claims 6-13 was not proper. At the least, if a restriction requirement or election of species requirement was to be made, Applicants should have been given the opportunity to make an election since none of the claims are independent and distinct from the originally presented claims to warrant a constructive election.

**Claims 6-13 Are Not Rendered Obvious By Silvestrini in View of Vert or Tormala**

According to the Examiner, Silvestrini does not disclose resorbable reinforcing elements but requires fibers of high strength and modulus. The Examiner further states that the materials of Vert and Tormala possess good strength and modulus and may be used to provide the fibers in the fabric of Silvestrini with high strength and modulus. The Examiner concludes that it would have been obvious "to use the resorbable composite material of either of Vert et al or Tormala et al as the resorbable component of Silvestrini et al since high strength and modulus is required." Applicants respectfully traverse this rejection as there is no motivation or suggestion either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the teachings of the references to produce the surgical implant as recited in claim 6.

Accordingly, a *prima facie* case of obviousness has not been established.

Silvestrini describes a triaxially-braided fabric that has overall "high elasticity" and "high strength." Silvestrini provides ample disclosure on how to fabricate a fabric having such purported mechanical properties and what factors to consider. For example, Silvestrini provides a long list and table of several polymers from which the fibers of the fabric can be made. Silvestrini also states that "aside from the materials selected for the three sets of fibers. . . the resulting mechanical properties of the prosthesis can be "materially affected by the various braiding variable, e.g. the fiber diameters, braiding angle, braiding tension, density of windings, number ratio of fibers in the thread sets of braiding pattern." Col. 6, lines 36-41. In addition, Silvestrini states that "of considerable importance is the braiding angle. . . and the resistance of prosthesis 1 to deformation under axial loading in tension increases as the braiding angle is decreased." Applicants submit that one skilled in the art confronted with the problem of trying to achieve high

strength and modulus in an implant, would not be motivated to combine the teaching of Vert or Tormala, which teach achieving mechanical strength properties, with the teaching of Silvestrini, as Silvestrini has already provided a purported solution to this problem. There is no suggestion that the resorbable composite material of Vert or Tormala should be used instead of the material of the fabric of Silvestrini to solve the above-mentioned problem.

Furthermore, using the resorbable composite material of Vert or Tormala as the material of the fabric of Silvestrini would change the principle of operation of Silvestrini. Silvestrini described a triaxially-braided fabric contains interwoven first, second, and third sets of fibers. Col. 2, lines 28-29. As stated by Silvestrini, "the fibers of the first set have greater elasticity, than the fibers of both of said second and third sets, and the fibers of the second and third sets have greater yield strength and Young's modulus than the fibers of the first set." See col. 2, lines 45-49. Therefore, the principle of operation of the Silvestrini fabric is achieving overall high strength and high elasticity by using fibers having different mechanical properties (*i.e.* either high strength or high elasticity) and then weaving these fibers together. Using the resorbable composite material of Vert or Tormala as the material of the fabric of Silvestrini would change the principle of operation of the Silvestrini fabric because then the material of the fabric would have uniform mechanical properties instead of different mechanical properties in different parts of the fabric.

For at least these reasons, Applicants submit that there is no motivation to combine the teachings of Silvestrini with the teachings of Vert or Tormala and that accordingly, a *prima facie* case of obviousness has not been established for claim 1 (and all claims that depend therefrom).


CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees are required in connection with the filing of this response, such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,  
KENYON & KENYON

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By: Zeba Ali  
(Reg. No. 51,392)

1500 K Street, N.W.  
Washington, D.C. 20005  
Tel: (202) 220-4200  
Fax: (202) 220-4201  
494334v2 (DC01)